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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,205	08/08/2003	Terrence S. McGrath	6619-85-1CON	4081
30448	7590	07/26/2006	EXAMINER	
AKERMAN SENTERFITT			EBRAHIM, NABILA G	
P.O. BOX 3188			ART UNIT	PAPER NUMBER
WEST PALM BEACH, FL 33402-3188			1618	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/637,205	MCGRATH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 4/6/06.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2,4-8,10,11 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,4-8, 10,11, 13-19 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/7/06 has been entered.

#### ***Prosecution***

The prosecution of the instant application has been transferred from Examiner Berko Retford to Examiner Nabila Ebrahim.

#### ***Status of Claims:***

Claims 1, 8, 10, 13-16, and 18 and cancelled.

#### ***Claim Rejections - 35 USC § 112***

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites a "to skin or other tissue surface external to the body of the mammal". The meaning of "other tissue surface external to the body of the mammal" is not clear. An explanation is required.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4-6, 8, 10, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by White US 4366169.

White discloses a method of treating a wound involves contacting the wound with a molecular oxygen containing member of a family of materials popularly known as synthetic blood or blood substitutes (col. 2, lines 61+) and the carrier comprises water (col. 4, line 43). Among the skin problems treated by the method are burns (col. lines 50+). Oxygen can be added to the material by many different means; one example of which would be to bubble 100% oxygen through the material (col. 4, lines 37+). White teaches that Burns are the primary example and healing of damaged tissue characteristic of burns can be accelerated by increasing the amount of oxygen at the damaged tissue. Oxygen tents surrounding the entire victim or the burn area (hyperbaric chambers) have been used but not overly successfully because they present safety problems, the exchange rate of the oxygen and damaged tissue is not remarkably better, and they do not always eliminate bacterial infections which are prone to occur during the healing period. Accordingly, the invention as increasing the concentration of oxygen in the burned area will consequently improve the bacterial infection. White adds that Contacting as used herein refers to a local application and excludes the use of perfluorocarbons in the blood system (col. 5, lines 45+). In addition, the reference discloses that The contacting in most cases will be by application to the skin surface, as described before, but does not exclude application to non-skin surfaces by means other than the blood system. Examples of the latter applications include

applications to respiratory mucous surfaces by tubes, etc., and the like (col. 5, lines 49+), and explains that the ability to transport oxygen is related to the solubility of oxygen in the materials and suggest that the perfluorinated materials will absorb 10-100 cc of oxygen per 100 cc of material at 25°C. and 760 milliliters of mercury. The substantially fluorinated carbon materials, i.e., perfluorocarbons, which can be used with this invention will have similar oxygen transport abilities (col. 4, lines 15+). The contacting of a burn victim with the perfluorocarbon can occur by various means. For example, one embodiment involves the immersion of the victim in a bath of the material maintained at a suitable temperature for the victim's comfort (col. 4, lines 65+), the disclosure reads on the recitation of the temperature of instant claim 11 of a temperature between 0 and 34°C, this temperature encompass a comfortable bath temperature, and also reads on the whirlpool bath of instant claim 17 because according to white, the bath should be recirculated through cleansing means which suggest a simulation of a whirlpool with agitation. The vehicle can be in the form of a gel or a spray (claim 17).

Note that the instant application defines The superoxygenated compositions of the present invention as comprise at least about 55 ppm oxygen but find useful concentrations from about 45 to about 220 ppm. The oxygen level in the compositions depends on several factors, including the type of composition, the temperature, and other components, active or not, that may be added for various reasons such as stability, ease of application or to enhance absorption [0020]. Accordingly, White's composition reads on the instant definition.

Also the limitation of time sufficient to increase the subepithelial partial oxygen pressure from about 30% to about 120% above baseline pO<sub>2</sub> is considered inherent since the disclosed method of the prior art would cause the same effect on healing of the wound or burn.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-8, 10, 11, 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over White US 4366169 in view of Ladin et al US 5, 792, 090 further in view of Kolta et al US 6, 139, 876.

White is applied as discussed hereinabove.

White does not specifically disclose use of the method to treat anaerobic bacteria, the oxygen bubble size.

Ladin discloses a method of healing of surface wounds, including burns, which is facilitated by increasing the wound oxygen tension through the application of an oxygen-generating wound dressing which renewably and non-sustainingly chemically generates oxygen. The wound dressing contains an oxygen permeable membrane and an oxygen supply solution. Because the oxygen chemically produced by the subject invention may include both gaseous oxygen as well as dissolved oxygen, the membrane pore sizes of from 0.01 to 10 micron, preferably 0.1 to 1.0 microns are preferred to limit the oxygen passage (col. 5, lines 16+)

Kolta discloses a gelatin with increased oxygen content for pharmaceutical, cosmetic and/or veterinary use. The gelatin comprises a gelling agent and a solvent, furthermore oxygen in a substantially even distribution with a pressure exceeding normal atmospheric pressure (abstract). Kolta teaches that gelatin and the oxygen encapsulated therein will have special synergistic effects. The intensive presence of oxygen will prevent proliferation of anaerobe bacteria which otherwise would rapidly multiply in the gelatin (col. 2 line 12+)

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to expand the teaching of White by realizing a fine size of the oxygen bubbles because the size of the bubble relate inversely with the penetration of the tissue and also to ensure the effect of the method on the anaerobic bacteria because Kolta discloses that the presence of oxygen ensures the prevention of

proliferation of anaerobic bacteria. The expected result would be a method for increasing skin oxygenation by applying a composition of high oxygen concentration to a wound, or burn in a topical application or a bath.

***Correspondence***

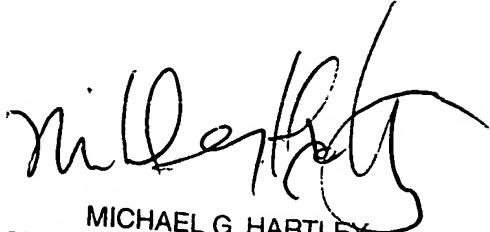
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim

6/6/06



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER